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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,664	05/02/2005	Andrzej Czernecki	POL0005-PCT	5014
28970	7590	09/11/2006	EXAMINER	
PILLSBURY WINTHROP SHAW PITTMAN LLP 1650 TYSONS BOULEVARD MCLEAN, VA 22102			TOWA, RENE T	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/506,664	CZERNECKI ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Rene Towa	3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 08 June 2006.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-19 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-19 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

1. This Office is responsive to an amendment filed June 8, 2006. Claims 1-19 are pending. Claims 1-4 are amended. Claims 5-19 have been added. No claim has been cancelled.

### ***Claim Objections***

2. Claims 5-11 and 13-19 objected to because of the following informalities:  
at line 1 of the claims, insert --wherein-- before "the."  
Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rutynowski et al. (US Patent No. 6,613,064) in view of Chelak et al. (US Patent No. 6,558,402).

In regards to claims 1 & 3-4, Rutynowski et al. disclose a device for puncturing patient's skin comprising a sleeve 1, a push element 2 mounted on one end of the sleeve 1, a piston 5 with puncturing tip 8 slidably mounted inside the sleeve 1, and a drive spring 10 positioned between the face of the push element 2 and the piston 5, wherein at the other end of the sleeve 1 an indicating-adjusting member 3, comprising an opening 4 for the puncturing tip 8 and comprising inwardly directed stair shaped limiting members, which are capable of being hit in operation by the fin 7 of the piston 5, is mounted turnably with respect to the axis of the sleeve, wherein the indicating-

adjusting member 3 has at least one indicator 16 of the pre-set puncturing depth 17 (see figs. 1-2 & 4; column 2/lines 1-7; see claim 3 of Rutynowski et al.).

In regards to claim 8, Rutynowski et al. disclose a device wherein the piston having a wing 12 resting on an edge 13 of the sleeve 1, the wing 12 configured to prevent the piston 5 from sliding through the sleeve 1 (see fig. 4; column 2/lines 11-22).

In regards to claim 9, Rutynowski et al. disclose a device wherein the puncturing force adjusting member 3 adjusting a distance within which a return spring 11 is compressed when the inwardly directed pair of oblique half-ring members press against the piston 5 (see fig. 4).

In regards to claim 10, Rutynowski et al. disclose a device wherein the piston having a wing 12 resting on an edge 13 of the sleeve 1, the wing 12 configured to prevent the piston from sliding through the sleeve 1, the drive spring 10 compressed until the piston is sufficiently pressed enough to break the wing 12, at which point the drive spring 10 expands and drives the piston 5 (see fig. 4; column 2/lines 11-22).

In regards to claim 11, Rutynowski et al. disclose a device wherein the puncturing force adjusting member 3 adjusting a distance within which the return spring 11 is compressed when the inwardly stair shaped members press the piston 5 (see fig. 4; claim 3 of Rutynowski et al.).

Rutynowski et al. teach a device, a described above, that teaches all the limitations of the claims except Rutynowski et al. do not teach an indicator of the pre-set puncturing depth that is located in a circumferential groove and is visible within

external cut-outs; Rutynowski et al. further do not teach a puncturing-force adjusting member that extends from the push element and presses against the top portion of the piston and drive spring. However, Chelak et al. disclose a system as follows:

In regards to claim 1, Chelak et al. disclose a system comprising an indicator 113 of the pre-set puncturing depth located in the a circumferential groove with an external cut-out (112, 331) (see figs. 1, 3D, 4A-C, 4E-G & 7-8; column 4/lines 49-60; column 7/lines 57-66; column 8/lines 46-47, 55-57 & 64-65; column 9/lines 51-58; column 10/lines 15-19; column 12/lines 56-57 & 63-67; column 13/lines 8-19 & 51-60).

In regards to claim 5, Chelak et al. disclose a system wherein the indicator (113, 349) comprises a protrusion (106, 349) protruding from the indicating-adjusting member (108, 308) in a direction parallel to the axis of the sleeve (136, 328) (see figs. 3D & 7-8).

In regards to claim 6, Chelak et al. disclose a system wherein the device comprises an inner wall (106, 306) and outer wall (104, 304) that define the circumferential groove (see figs. 1, 3D, 4A-C, 4E-G & 7-8).

In regards to claim 7, Chelak et al. disclose a system wherein the indicator (113, 349) is visible through the cut-out (112, 331) (see figs. 1, 3D, 4A-C, 4E-G & 7-8; column 7/lines 57-66; column 12/lines 56-57 & 63-67; column 13/lines 8-19).

In regards to claim 1 & 5-7, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Rutynowski et al. with an indicator similar to that of Chelak et al. in order to facilitate an adequate, reproducible lancing for the user or patient (see Chelak et al., column 4/lines 25-29).

Moreover, in regards to claim 2, since Chelak et al. discloses a plurality of cut-outs 331 of different lengths (see figs. 7-8 & 10B), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Rutynowski et al. as modified by Chelak et al. with a plurality of cut-outs having different widths since such a modification would amount to a design choice that would serve the same purpose of indicating the depth of penetration (see Chelak et al., column 13/lines 51-60).

Furthermore, in regard to claims 3-4, 9 & 11, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Rutynowski et al. as modified by Chelak et al. with a force adjusting member that extends from the push element and presses against the top portion of the piston and drive spring since such a modification would amount to a design choice. It has previously been held that shifting location of parts (i.e. shifting location of the depth or force indicating-adjusting member) is not patentable--See *In re Japikse*, 181 F. 2d 1019, 1023, 86 USPQ 70, 73 (CCPA 1950). Moreover, it has also previously been held that reversing location of parts is not patentable--*In re Gazda*, 219 F. 2d 449, 452, 104 USPQ 400, 402 (CCPA 1955).

5. Claims 12-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rutynowski et al. (US Patent No. 6,613,064).

In regards to claim 12, Rutynowski et al. disclose a puncturing device for regulating force of puncture comprising:

a sleeve 1 having a first end and second end, and defining a sleeve axis;  
an adjustable push element 2 located at the first end of the sleeve;  
a piston 5 slidably mounted within the sleeve 1, the piston 5 having a wing 12  
configured to rest on an edge of the sleeve 1 and prevent the piston 5 from sliding  
through the sleeve 1, and the piston 5 having a puncturing tip 8 on a side of the piston  
5 opposite to the first end of the sleeve 1; and  
a drive spring 10 within the sleeve 1 and compressed between the adjustable  
push element 2 and the piston 5,  
the adjustable push element 2 configured to change the distance between the  
adjustable push element 2 and the piston 5, and  
the drive spring 10 being compressed until the push element 2 presses the piston  
5 sufficiently enough to break the wing 12, at which point the drive spring 10 expands  
and drives the piston 5 toward the second end of the sleeve 1 (see figs. 1-2 & 4;  
column 2/lines 1-7 & 11-22; see claim 3 of Rutynowski et al.).

In regards to claims 12-16, Rutynowski et al. further discloses a member 3  
configured to press against the piston 5 in a direction parallel to the sleeve axis,  
wherein the member 3 having an edge, and the edge having a gradient such  
that a height of the edge varies;

wherein pressing of the piston 5 causes a different portion of the edge of the member 3 to press the piston 5;

wherein the member 3 comprises an oblique half-ring member.

wherein the member 3 comprises stair shaped members.

In regards to claim 17, Rutynowski et al. disclose a device wherein the wing 12 configured to rest on an upper edge 13 of the sleeve 1 (see fig. 4).

In regards to claim 18, Rutynowski et al. disclose a device wherein the piston 5 having a second wing 12 configured to rest on an edge 13 of the sleeve 1 (see fig. 4).

In regards to claim 19, Rutynowski et al. disclose a device wherein the piston comprising a central body 5, a push rod 6 on a side of the central body proximate to the first end of the sleeve 1, and a fin 7 on a side of the central body proximate the second end of the sleeve 1 (see figs. 1-2 & 4).

Rutynowski et al. disclose a device, as described above, that teaches all the limitations of the claims except Rutynowski et al. do not disclose a puncturing-force adjusting member that extends from the push element and presses against the top portion of the piston and drive spring. However, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Rutynowski et al. with a force adjusting member that extends from the push element and presses against the top portion of the piston and drive spring since

such a modification would amount to a design choice. It has previously been held that shifting location of parts (i.e. shifting location of the depth or force indicating-adjusting member) is not patentable--See *In re Japikse*, 181 F. 2d 1019, 1023, 86 USPQ 70, 73 (CCPA 1950). Moreover, it has also previously been held that reversing location of parts is not patentable--*In re Gazda*, 219 F. 2d 449, 452, 104 USPQ 400, 402 (CCPA 1955).

### ***Response to Arguments***

6. Applicant's arguments, filed June 21, 2006, regarding the teachings of an external cut-out with respect to the rejection(s) of claim 1 under 102 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Chelak et al., as established the rejections supra; wherein Chelak et al. discloses an indicating-adjusting member (108, 308) located in a circumferential groove with external cut-outs (112, 331).

7. Applicant's arguments regarding the alleged nuance between a depth-adjusting member and a force-adjusting member have been fully considered but they are not persuasive. Applicant contends a depth-adjusting member is different from a force-adjusting member. This argument has been considered and has not been deemed persuasive.

In regards to the Applicant's argument, the Examiner respectfully disagrees.

First, a depth-adjusting member (see rejections above) comprises each and every structural element of a force-adjusting member. The Applicant is thus reminded that a recitation of the intended use of the claimed invention must result in a structural

difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Second, a depth adjusting-member appears to be capable of controlling depth of penetration by controlling the force since the system may be governed by the following equation:

$$F = kX ,$$

where F is the force, k is the spring constant and X is the depth. Clearly, one needs to reduce or adjust the force in order to thereby reduce or adjust the depth and vice-versa. As such, the Examiner submits that teaching of depth adjustment is sufficient to imply teaching of adjustment of force since a depth-adjusting member may well be construed as force-adjusting member, in part, for their structural likeness. In view of the foregoing, the Examiner respectfully submits that Rutynowski et al. teaches a depth or force adjusting member 3 as established in the rejections supra. Moreover, it has previously been held that shifting location of parts (i.e. depth or force adjusting member) is not patentable--See *In re Japikse*, 181 F. 2d 1019, 1023, 86 USPQ 70, 73 (CCPA 1950).

### ***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 6,645,219 to Roe discloses a rotatable penetration depth adjusting arrangement.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RTT



MAX F. HINDENBURG  
SUPERVISORY PATENT EXAMINER  
TELEPHONE 272-4726 FAX 273-8300